REMARKS

This is a full and timely response to the Office Action mailed August 7, 2003.

By this Amendment, claim 13 has been added to further protect a specific embodiment of the present invention. Support for this new claim can be found throughout the specification, for example, at page 9, lines 1-8. No new matter was added. Claims 1-13 are pending in this application. In view of this Amendment, Applicant believes that all pending claims are in condition for allowance. Reexamination and reconsideration in light of the above amendments and the following remarks is respectfully requested.

Rejections under 35 U.S.C. §102

Claims 1-6 and 11 are rejected under 35 U.S.C. §102(b) as anticipated by Steiner et al., (Nucleic Acids Research, vol. 23, no. 13, 2569-2570 (1995)) ("Steiner"). Applicant respectfully traverses this rejection.

Claim 1 includes the transitional phrase "consisting essentially of", and therefore, the claim is limited to the specifically claimed materials ***"and those that do not materially affect the basic and novel characteristic(s) of the claimed invention"***. The claims would, therefore, not encompass other ingredients, such as PVPP, if they materially affect the basic and novel characteristic(s) of the claimed invention.

The basic and novel characteristics of the present invention is a method of synthesizing nucleic acids by homogenizing a living body-derived sample to produce a homogenized sample consisting essentially of said living body-derived sample and a surfactant; and then directly adding the homogenized sample to a PCR reaction solution to amplify the nucleic acid. This claimed method allows for the synthesis of nucleic acids without the need for (1) isolating and purifying gene inclusion bodies and the nucleic acids contained therein, and (2) agitating the sample to uniformly distribute the solid components in the sample.

In contrast, Steiner discloses that a plant tissue can be ground into dry material, and a rapid one-step **extraction** (ROSE) buffer containing 1% sodium lauryl sarkosyl can be added to the ground lyophilized tissue (see page 2569, column 1, of Steiner). Steiner also discloses that 400 µl of ROSE containing 1% sodium lauryl sarkosyl is added to a 100 µl human blood sample (see page 2570, col. 1-2), and polyvinylpolypyrrolidone (PVPP) is added to the ground lyophilized tissue. In other words, Steiner's combination of the tissue and the ROSE buffer

contains PVPP. Although ROSE contains a surfactant, it is clear that ROSE also includes additional compounds such as 1% polyvinylpolypyrrolidone (PVPP).

As stated in the specification (pages 2 and 3), an ion-exchange resin, a glass filter, or a reagent having an effect of agglutinating proteins have been used in the step of nucleic acid extraction (see page 2, lines 22-24, of the specification) prior to PCR. The amount of nucleic acids in a sample recovered by these purification procedures often varies among experiments. Often, after such purification procedures, nucleic acid synthesis via PCR may sometimes be unsuccessful, especially when the content of the intended nucleic acid in the sample is low (see page 3, lines 2-6, of the specification). Also, these purification procedures are inefficient and burdensome since they are time-consuming and involve complicated manipulations (see page 3, lines 6-8, of the specification).

Steiner's PVPP is a kind of additive which has an effect of agglutinating proteins and which has been added to the sample for **nucleic acid extraction**. In other words, the ROSE buffer containing PVPP in Steiner is added to the sample to allow the tissue and PVPP to settle. In this settling process, it is very likely that some of the nucleic acid extracted by the ROSE Buffer combined with the settling tissue and PVPP and trapped in the settled tissue and PVPP. This effect obviously results in a lower amount of recovered nucleic acid to be stored or used for amplification. Thus, even though Steiner's method is a completely self contained **extraction** environment which requires no further transfer or addition step, the presence of PVPP still causes variations in the amount of nucleic acids in the buffer since different kinds of nucleic acid have different proclivities toward being entrapped by the settling tissue. Therefore, the presence of PVPP ***materially affect the basic and novel characteristic(s) of the claimed invention***" since the disadvantages noted in the specification are present in the method taught by Steiner.

In addition, Steiner's technique requires a heat treatment of "90°C for 20 min" (see page 2569, line 31, of Steiner) due to the use and presence of PVPP. This makes the Steiner technique more time-consuming and complicated than the present invention which also materially affects the basic and novel characteristics of the present invention.

Thus, for these reasons, this rejection should be reconsidered and withdrawn.

Claim 12 is rejected under 35 U.S.C. §102(b) as anticipated by Liu et al. ("Effects of three Sample Preservation Method on Total DNA Preparation of Porcine Whole Blood," Di-San

Junyi Daxue Xuebao vol. 21, no. 1 (1999)) (hereinafter "Liu"). Applicant respectfully traverses this rejection.

Claim 12 recites a method of sample storage, which comprises homogenizing a living body-derived sample to produce a homogenized sample consisting essentially of said living body-derived sample and a surfactant; and then storing the homogenized sample in homogenized state until amplification of a nucleic acid. The basic and novel characteristic of this claimed method involves allowing a living body-derived sample to be stored over a long period of time in a homogenized state without agitation.

As shown in Experimental Example 2 of the specification, in which the blood sample was prepared using the method of the present invention and stored for 10 months at room temperature, a PCR product from the sample could still be detected stably and strongly, same as in Experimental Example 1 in which the sample was immediately used.

In contrast, Liu discloses the opposite result in their investigation of three blood sample preservation methods. In method (3), Liu stored at room temperature the blood sample after mixing the sample with SDS-EDTA. Liu describes that the "DNA was destroyed to some extent" (see line 26 of Liu). In other words, Liu teaches that blood samples cannot be stored for a long period following the addition of SDS-EDTA to the blood samples.

A document can only anticipate a claim if the document discloses, explicitly or implicitly, each and every feature recited in the claim. Verdegall Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Since Liu fails to teach from its experimental results the method of the present invention, the rejection should be reconsidered and withdrawn.

CONCLUSION

For the foregoing reasons, claims 1-13 are allowable, and the present application is in condition for allowance. Accordingly, favorable reexamination and reconsideration of the application in light of these amendments and remarks is courteously solicited. If the examiner has any comments or suggestions that would place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number below.

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Respectfully submitted,

By_____

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